Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of preventive effects of Ketamine ,fentanyl and paracetamol on Hemodynamic parameters and acute postoperative pain after deep vitrectomy

Protocol summary

Study aim

Determining the effect of prophylactic administration of ketamine, fentanyl and paracetamol on hemodynamic parameters and severity of acute pain after deep vitrectomy and comparison with control group

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 80 patients. Random allocation software is used for randomization

Settings and conduct

Randomized double-blind clinical trial (physician and patient and data analyzer are not aware of the type of drug combination used) which is performed in 2021 in Feyz Educational-Medical Center of Isfahan Before starting the project, the sequence of patients in 4 groups is determined using random allocation software and patients are divided into 4 groups receiving ketamine , group receiving fentanyl , paracetamol receiving group and control group. they take 15 minutes before the operation with the coordination of the surgeon of the studied drugs Will be given intravenously And delivered in covered syringes with a code. The medicine is prepared by an operating room technician and the doctor is unaware of the contents of the syringe

Participants/Inclusion and exclusion criteria

inclusion criteria : Patients in the age range of 40-80 years, with ASA class 1 and 2, candidates for elective deep vitrectomy under general anesthesia exclusion criteria : Pregnancy, history of smoking, drug and alcohol addiction, if the duration of surgery is less than one and more than three hours

Intervention groups

Patients in the intervention group include canide patients undergoing vitrectomy receiving fentanyl, paracetamol, and ketamine. Patients in the intervention group include canidectomy patients receiving normal saline serum.

Main outcome variables

Evaluation of hemodynamic changes after deep vitrectomy surgery; Evaluation of pain after deep vitrectomy surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201213049697N1**
Registration date: **2021-09-07, 1400/06/16**
Registration timing: **retrospective**

Last update: **2021-09-07, 1400/06/16**
Update count: **0**

Registration date

2021-09-07, 1400/06/16

Registrant information

Name

Mohamad Razani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-16, 1399/09/26

Expected recruitment end date

2021-08-22, 1400/05/31

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of preventive effects of Ketamine ,fentanyl and paracetamol on Hemodynamic parameters and acute postoperative pain after deep vitrectomy

Public title
Comparison of preventive effects of Ketamine ,fentanyl and paracetamol on Hemodynamic parameters and acute postoperative pain after deep vitrectomy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
all patient candidate for deep vitrectomy surgery
Exclusion criteria:
each surgery that long more than 3 or less than 1 hour pregnancy addiction to cigarette ,opium and alcohol Inability to speak non iranian nationality more than 100 kg weight choronic pain that last more than 6 month uncontroled systemic diseases such as liver or kidney disease allergy or anaphylaxy to NSAID ,opium and drug that we use in study psychosis ,obvious anxiety before surgery and History of taking anti-anxiety medication
Age
From **40 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Before starting the project, the sequence of patients in 4 groups is determined using random allocation software And patients are divided into 4 groups receiving ketamine (group K), group receiving fentanyl (group (f), group receiving paracetamol (group p) and control group It(drug) is delivered in covered syringes and has a code. The medicine is prepared by an operating room technician and the doctor is unaware of the contents of the syringe. Randomization is simple. It is an individual randomization unit. Randomization is done by random allocation
Blinding (investigator's opinion)
Double blinded
Blinding description
Prior to surgery, patients will be told that their pain intensity and hemodynamic parameters will be assessed after surgery, patients will be told if they are compared to other groups, and then their consent form will be obtained Becomes The medicine is prepared by an operating room technician and the doctor is unaware of the contents of the syringe In order for the study to be bi-blind, two different people will be used so that the anesthesiologist will prescribe the medication And the other person does not know the type of drug used Collects data and analyzes information. In fact, the drugs are prepared by the anesthesia technician and delivered to the anesthesiologist in sealed and numbered syringes. The anesthesiologist does not know the type of drug injected into the patient. Also, data related to the study during and after the operation will be collected and analyzed by someone other than the anesthesiologist and anesthesiology Technician
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
esfahan university of medical science, Hezar jarib Ave ,Darvaze shiraz square
City
esfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2020-12-03, 1399/09/13
Ethics committee reference number
IR.MUI.MED.REC.1399.787

Health conditions studied

1

Description of health condition studied
Most cases of vitrectomy are performed due to retinal detachment for any reason, including diabetes, trauma, etc.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Hemodynamic changes (blood pressure, respiration rate, heart rate, blood oxygen saturation)
Timepoint
Before the operation, during the operation (at intervals of 15 minutes, 30 minutes, one hour, two hours), after the operation (at intervals of 15 minutes, 30 minutes, one hour, two hours, 4 hours, 16 hours , 24 hours)
Method of measurement
Mercury sphygmomanometer, clock, pulse oximeter

2

Description
Acute pain after surgery
Timepoint
Before the operation, during the operation (at intervals of 15 minutes, 30 minutes, one hour, two hours), after the operation (at intervals of 15 minutes, 30 minutes, one hour, two hours, 4 hours, 16 hours , 24 hours)
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Ketamine (Group K) 0.5mg / kg will be opened by intravenous infusion within 15 minutes after the volume of the above drugs is increased to 100 cc by sterile normal saline solution .Drug of a special pharmaceutical factory is not consider .The duration of the patient follow-up period after injecting drugs is 24 hours, which the patient's vital signs, pain intensity, and medications are recorded at specified intervals.
Category
Treatment - Drugs

2

Description
Intervention group: The fentanyl group receiving 2mcg / kg will be infused intravenously within 15 minutes after the volume of the above drugs is increased to 100 cc by sterile normal saline solution. Drug of a special pharmaceutical factory is not consider . The duration of the patient follow-up period after injecting drugs is 24 hours, which the patient's vital signs, pain intensity, and medications are recorded at specified intervals.
Category
Treatment - Drugs

3

Description
Intervention group: Paracetamol group receiving 10 mg / kg will be infused intravenously within 15 minutes after the volume of the above drugs is increased to 100 cc by sterile normal saline solution. Drug of a special pharmaceutical factory is not consider . The duration of the patient follow-up period after injecting drugs is 24 hours, which the patient's vital signs, pain intensity, and medications are recorded at specified intervals.
Category
Treatment - Drugs

4

Description
Control group: 100 cc normal saline for 15 minutes intravenously
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Feiz hospital
Full name of responsible person
Mohamad Razani
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Isfahan - Ghods Square - Modares Street - Feyz Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Darioush Moradi Farsani

Position

Associate professor

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

In this study, only data related to the effect of drugs on hemodynamic parameters and acute postoperative pain will be published and potential data information will be published only after the necessary coordination with the executor and ensuring the scientific rank and purpose of the person requesting the information.

When the data will become available and for how long

One year after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

The data will be provided to the mentioned people for comparative studies as well as systematic studies

From where data/document is obtainable

razani113774@gmail.com ,Mohammad Razani, Isfahan University of Medical Sciences 09381793755

,Mohammad Razani, Isfahan University of Medical Sciences

What processes are involved for a request to access data/document

Depending on the type of information requested, the person communicates with the researcher through the channels provided and finally receives his / her answer within one month.

Comments